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510(K) SUMMARY.

Submitted by: Mr. Robert Shaw.
Vice President.
Owen Mumford Incorporated.
1755 – A West Oak Commons Court.
Marietta.
Georgia 30062.
USA.

Tel: 770-977-2226.
Fax: 770-977-2866.

Device Name: EZ Syringe.
Classification Name: Piston Syringe, Accessory.
Predicate Device: Inject-Ease (K872233).

Owen Mumford Limited has been successfully marketing syringe needle introducers throughout the world since 1986.

These products provide a safe and simple way to aid the patient in the home with a recommended treatment regime via a self-administered manual injection.

DEVICE DESCRIPTION.

The EZ Syringe O.T.C is a hand held, non-sterile manual device using 1 ml BD Hypak disposable glass pre-filled syringe.

The devices are designed for use with the 1 ml BD Hypak disposable glass syringe, and to accommodate self- use in the home by the patient or caregiver. The device incorporates enlarged wings to facilitate gripping and a semi-automatic feature to remove the needle shield of the Hypak syringe.

The device contains a number of features which adds to its safety and effectiveness, these are as follows:-

- Front twisting body with wings which easily removes the soft needle shield from the syringe.
- Large finger grip engineered to aid in the handling of the device.
- Allows the pre-filled syringe to be loaded and unloaded.
- Requires one turn to remove the needle shield.

INTENDED USE.

The hand held device is intended to aid in the self-administration of drugs from a pre-filled BD Hypak 1 ml disposable glass syringe. The device incorporates enlarged wings to facilitate gripping and a semi-automatic feature to remove the needle shield of the Hypak syringe.

OPERATIONAL.

The design concepts of the EZ Syringe submitted in this application are such that it makes the principal quite basic in its function to aid the patient in the home to support a manual injection.

PERFORMANCE.

A number of tests have been performed proving the correct action of a wide range of functions for the EZ Syringe, they are:-

- Parking Action of Boot Remover.
- Drop Test.
- Environmental

The performance testing completed under section 6 of this 510(K) submission indicates that the device performs within the agreed specification and is safe and reliable.

USER TRIAL.

The correspondence included in section 9 of this over – the – counter submission clearly indicates the success of the device for patient or carer preference for carrying out a manual injection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 2 2001

Mr. Robert Shaw
Vice President
Owen Mumford, Limited
1755 A West Oak Commons Court
Marietta, Georgia 30062

Re: K011951
Trade/Device Name: EZ Syringe
Regulation Number: 880.5860
Regulatory Class: II
Product Code: FMF
Dated: June 21, 2001
Received: June 21, 2001

Dear Mr. Shaw:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number: (Unknown).

Device Name: EZ – Syringe O. T. C.

Indications for Use:

The hand held device is intended to aid in the self-administration of drugs from a pre-filled BD Hypak 1 ml disposable glass syringe. The device incorporates enlarged wings to facilitate gripping and a semi-automatic feature to remove the needle shield of the Hypak syringe.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of the CDRH, Office of Evaluation (ODE)

Prescription Use:..... Over-The -Counter Use:✓.....
(Per 21 CFR 801.109)

Sabrina Cuccinotta
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011951